IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Cuyahoga v. Purdue Pharma L.P., et al.*, Case No. 17-op-45004 and *The County of Summit, Ohio, et al. v. Purdue Pharma L.P, et al.*, Case No. 18-op-45090.	MDL No. 2804 Case No. 1:17-md-2804 Hon. Dan Aaron Polster

NON-RICO SMALL DISTRIBUTORS' REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT ON PLAINTIFFS' "FAILURE TO REPORT" AND "FRAUD ON THE DEA" CLAIMS

I. The Sixth Circuit forbids "savvy plaintiffs" to avoid *Buckman* preemption by dressing up their claims with state-law labels.

As set forth in the Non-RICO Small Distributors' opening Memorandum (ECF #1873-1 at 2-3, 5), in which Henry Schein, Inc. and Henry Schein Medical Systems, Inc. were co-movants,[1] Plaintiffs' specific allegations of negligence *per se* and many other allegations, as well as their Interrogatory responses, relied exclusively—or heavily—on alleged violations of the CSA and its implementing regulations, and on allegations of "Fraud on the DEA." Plaintiffs have never dismissed, amended, or withdrawn these allegations and discovery responses. Further committing themselves to their theory that alleged violations of the CSA govern their cases entirely, Plaintiffs filed two motions for partial summary judgment confirming such allegations are the very heart of their claims.[2]

Ignoring all this, Plaintiffs now argue that their "claims against the Small Distributors are not predicated on an allegation that they defrauded the DEA," and are instead "based on the Small Distributors' tortious conduct in failing to stop shipments of suspicious orders" and "Ohio common and statutory law . . . even if the Small Distributors' conduct *also* violates obligations under the CSA." ECF #2171, at 8. (original emphasis). The Sixth Circuit has repeatedly pierced such wordplay. For instance, in *Loreto v. Procter & Gamble Co.*, 515 Fed. App'x 576 (6th Cir. 2013), the court held that, under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), "[t]he statute's public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law . . . a claim that in substance seeks to enforce the FDCA. Under principles of 'implied preemption,' therefore, private litigants may not 'bring a state-law claim against a

[1] The Court granted *Track One* Plaintiffs' Severance Motion as to several of the Non-RICO Small Distributors. Plaintiffs did not move to sever Henry Schein, Inc. and Henry Schein Medical Systems, Inc. The Henry Schein entities remain in the first bellwether trial scheduled for October 2019; this motion should be decided before the trial. *See* ECF # 2399 at 3.

[2] *See* Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act and their Motion for Partial Summary Adjudication that Defendants Did Not Comply With Their Duties Under the Controlled Substances Act to Report Suspicious Opioid Orders and Not to Ship Them. ECF #'s 1877 and 1910.

defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA.'" 515 Fed. App'x at 579 (brackets and citations omitted). "If the defendant's conduct is not of [the] type [that would traditionally give rise to liability under state law] then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*." *Id*. (internal quotation marks and citation omitted); *see also McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 945 (6th Cir. 2018) (quoting *Loreto*, 515 Fed. App'x at 579).

The Sixth Circuit enforces *Buckman* preemption broadly, as "*Buckman* applies where an element of the claim is premised on a federal-law violation." *McDaniel*, 893 F.3d at 947 (internal quotation marks and citation omitted). *Buckman* also preempts claims alleging simple "non-compliance" with the federal scheme. *E.g.*, *Marsh v. Genentech, Inc.*, 693 F.3d 546, 555 (6th Cir. 2012) (holding that since plaintiff's claim "is premised on a violation of federal law, implicates the relationship between a federal agency and the entity it regulates, and asks the court to assume a role usually held by the FDA—and is thus preempted."); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2013 WL 587655, at * 14 (N.D. Ohio Feb. 13, 2013) (Polster, J.) (holding that this preemption principle "applies to every legal theory—whether the theory is ***part*** of a claim or remedy—that requires proof of fraud on, or misrepresentation to, the FDA") (citing *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004), emphasis added). *Buckman* preemption therefore applies here because Plaintiffs' claims include as "an element" alleged CSA violations, and that "theory is part of [their] claim."

Moreover, Plaintiffs failed to address the Small Distributors' Ohio federal decisions holding that Ohio common-law does not recognize any duty to not defraud a federal agency or to make reports to a federal agency that federal law might itself require. ECF #1873-1 at 3-5. More particularly, Plaintiffs failed to show—and cannot show—that they were "relying on

traditional state tort law which had ***predated*** the federal enactments in question." *Buckman*, 531 U.S. at 353 (emphasis added).[3] Thus, the Small Distributors' alleged conduct is not "the type of conduct that would traditionally give rise to liability under state law," *Loreto*, 515 Fed. Appx. at 579, Plaintiffs cannot be "relying on traditional state tort law that predated" the CSA, *Buckman*, 531 U.S. at 353, and Plaintiffs' claims are preempted.

Nor may Plaintiffs escape these settled rules by arguing that Ohio state courts allow evidence of federal law violations to support state law claims. ECF #2171 at 4. As the Small Distributors have already explained, this federal court is constrained by the subject matter jurisdictional limits and separation-of-powers principles in Article III, and may not indulge state law evidentiary rules to allow an escape from substantive federal law proscriptions, ECF #1873-1 at 5-7, points the Plaintiffs do not contest; *see also Jesner v. Arab Bank, PLC*, 138 S. Ct. 1386, 1410 (2018) (Thomas, J., concurring) ("Fidelity to congressional policy is not only prudent but necessary: Going beyond the bounds of Congress's authorization [to recognize a private cause of action under a federal statute] would mean unconstitutionally usurping part of the 'legislative Powers.'" (citing U.S. Const. art. I, § 1)).

II. *Wyeth v. Levine* does not limit *Buckman* preemption.

Plaintiffs wrongly argue that *Buckman* preemption has been nullified or limited by *Wyeth v. Levine*, 555 U.S. 555 (2009), on their theory that their claims serve as a "'complementary form of drug regulation.'" ECF #2171 at 3 (quoting *Wyeth*, 555 U.S. at 579). *Wyeth* was a product liability failure-to-warn case that did not involve an attempted private enforcement of the FDCA,

[3] For more than a century there have been known incidents where wholesale drug distributors grossly oversupplied morphine to a retail druggist acting in conspiracy with a physician to supply addicts and abusers—equivalent to "pill mills" today. *See Webb v. U.S.*, 249 U.S. 96, 98 (1919) (reviewing criminal convictions of a retail druggist and a physician under the 1914 Harrison Narcotic Drug Act, where "within a period of eleven months [a druggist] purchased from wholesalers … thirty times as much morphine as was bought by the average retail druggist doing a larger general business"). Yet, the Ohio Supreme Court did not respond to such known misconduct before (or after) the 1970 enactment of the CSA by imposing common-law duties on drug distributors to identify and report "suspicious orders" to federal authorities, and to not ship such orders, at the peril of incurring tort liability.

fraud on the agency, or "failure to report." The argument Plaintiffs seek to draw from *Wyeth* has been universally rejected. Instead, "[*Wyeth*] preserves common law state tort claims that parallel or reinforce the agency's efforts but do not involve the relationship between the federal regulator and the regulated entity, the dispositive factor for federal preemption in *Buckman*. In fact, neither the majority nor dissent in [*Wyeth*] cut back on *Buckman* or, indeed, found a state law fraud-on-the-agency theory viable in this broader context." *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 377 (5th Cir. 2012). Thus, "*Buckman* and *Wyeth* can be reconciled: while traditional state-law claims for failure to warn are not impliedly preempted by the FDCA, fraud-on-the-FDA claims are impliedly preempted by the FDCA." *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1323 (S.D. Fla. 2010); *see also Bower v. Johnson & Johnson*, 795 Fed. Supp. 2d 672, 675-76 (N.D. Ohio 2011).

And as shown above, the Sixth Circuit and this Court have continued to faithfully enforce and broaden *Buckman*'s teachings even long after *Wyeth* was decided, and these principles apply with equal strength to Plaintiffs' forbidden efforts to privately enforce the CSA.

III. Plaintiffs are wrong to mischaracterize 21 U.S.C. § 903 as a "savings clause."

Plaintiffs wrongly argue that 21 U.S.C. § 903 is a "savings clause" that permits their tort claims to proceed. ECF #2171 at 2, 9. But even if it were, "neither an express pre-emption provision nor a savings clause 'bars the ordinary working of conflict pre-emption principles.'" *Buckman*, 531 U.S. at 352 (brackets omitted, quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)). Moreover, as already explained, the Ohio Supreme Court did not impose any relevant common-law duties on wholesale distributors before (or after) the enactment of the CSA. Thus, there is no substantive Ohio state tort law to "save."

Plaintiffs' argument is particularly off-target because the Small Distributors have never argued field preemption; they have argued traditional conflict preemption. "Conflict pre-

emption may, of course, invalidate a state law even though field preemption does not." *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1602 (2015). And conflict preemption is exactly what § 903 preserves,[4] making it an ***express preemption*** clause: "The Supremacy Clause gives Congress the power to pre-empt state law expressly. Congress did just that in the CSA, which contains an express preemption provision: state law is preempted whenever 'there is a positive conflict between a provision of the CSA and a State law so that the two cannot consistently stand together.'" *Oregon Prescription Drug Monitoring Program v. DEA*, 860 F.3d 1228, 1235-36 (9th Cir. 2017) (quoting § 903, other internal quotation marks, brackets, and citation omitted).

IV. Plaintiffs have abandoned their claim that the Small Distributors' alleged failure to report enough "suspicious orders" to the DEA caused them damages.

"[A] plaintiff is deemed to have abandoned a claim when a plaintiff fails to address it in response to a motion for summary judgment." *Brown v. VHS of Mich.*, 545 Fed. App'x 368, 372 (6th Cir. 2013). In their Opening Memorandum, the Small Distributors demonstrated that Plaintiffs' claims that they were harmed by the Small Distributors' alleged failure to report enough "suspicious orders" to the DEA were barred, as a matter of law, because they were speculative and preempted, and Plaintiffs had no evidence to support those claims. ECF #1873-1 at 18. Plaintiffs' Opposition failed to address that argument and its supporting authorities, and Plaintiffs therefore must be deemed to have abandoned that claim.

CONCLUSION

For the foregoing reasons, Plaintiff's opposition arguments fail as a matter of law, and the Court should grant the Non-RICO Small Distributors' motion for partial summary judgment on Plaintiffs' failure to report and "fraud on the DEA" claims.

[4] As Plaintiffs' own Memorandum demonstrates, for more than a century federal regulation of opioids has been a model of cooperative federalism with the States. ECF #2171 at 3 (quoting 71 Fed. Reg. 52716-01, 52717. That is the long-standing cooperative regime preserved by § 903, as is more particularly described in § 873.

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Respectfully submitted,

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